(2) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any DC-defibrillator (including paddles) described in paragraph (b)(1) of this section that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a DC-defibrillator (including paddles) described in paragraph (b)(1) of this section that was in commercial distribution before May 28, 1976. Any other DC-defibrillator (including paddles) described in paragraph (b)(1) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 61 FR 50706, Sept. 27, 1996]

§ 870.5310 Automated external defibrillator.

(a) *Identification.* An automated external defibrillator (AED) is a low-energy device with a rhythm recognition detection system that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart. An AED analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

(b) *Classification.* Class III (premarket approval)

(c) *Date PMA or notice of PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

[68 FR 61344, Oct. 28, 2003; 69 FR 10615, Mar. 8, 2004]

§ 870.5325 Defibrillator tester.

(a) *Identification.* A defibrillator tester is a device that is connected to the output of a defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load. Some testers also provide waveform information.

(b) *Classification.* Class II (performance standards).

§ 870.5550 External transcutaneous cardiac pacemaker (noninvasive).

(a) *Identification.* An external transcutaneous cardiac pacemaker (noninvasive) is a device used to supply a periodic electrical pulse intended to pace the heart. The pulse from the device is usually applied to the surface of the chest through electrodes such as defibrillator paddles.

(b) *Classification.* Class II. The special controls for this device are:

(1) ''American National Standards Institute/American Association for Medical Instrumentation's DF–21 'Cardiac Defibrillator Devices' '' 2d ed., 1996, and

(2) ''The maximum pulse amplitude should not exceed 200 milliamperes. The maximum pulse duration should not exceed 50 milliseconds.''

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 65 FR 17144, Mar. 31, 2000]

§ 870.5800 Compressible limb sleeve.

(a) *Identification.* A compressible limb sleeve is a device that is used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb.

(b) *Classification.* Class II (performance standards).

§ 870.5900 Thermal regulating system.

(a) *Identification.* A thermal regulating system is an external system consisting of a device that is placed in contact with the patient and a temperature controller for the device. The system is used to regulate patient temperature.

(b) *Classification.* Class II (performance standards).

§ 870.5925 Automatic rotating tourniquet.

(a) *Identification.* An automatic rotating tourniquet is a device that prevents blood flow in one limb at a time, which temporarily reduces the total blood volume, thereby reducing the normal workload of the heart.